PCN167

INFORMING THE DECISION: IMPROVING GENERALIZABILITY BY PARAMETERIZING RELEVANT INFORMATION IN THE ECONOMIC EVALUATION OF TRASTUZUMAB IN EARLY BREAST CANCER

Joore MA[1], Hoomans T[2], Tjan-Heijnen V[1], Seferina S[1], Goettsch W[3], Grutters J[2]
[1]Maastricht University Medical Center, Maastricht, Limburg, The Netherlands; [2]Maastricht University, Maastricht, Limburg, The Netherlands; [3]Health Insurance Council, Diemen, Noord-Holland, The Netherlands

OBJECTIVES: To better inform decision-makers on how practice may deviate from scientific evidence, and for which factors further research is particularly worthwhile, through parameterizing factors that may impact the generalizability of economic evaluations. **METHODS:** We modeled the long-term cost-effectiveness of trastuzumab in early breast cancer. Based on a review, five real-world factors that could influence the cost-effectiveness of trastuzumab in daily practice were identified: comparators, patient consequences, clinical practice, patient mix, and professional use. To explore the impact of these factors on (cost-)effectiveness, parameters were added to the model. Parameter values, ranges, and distributions were based on literature and expert opinion. Analyses were performed without (trial scope) and with real-world factors included (decision scope). Cost-effectiveness acceptability curves were drawn and value of information was analyzed. **RESULTS:** In the trial-scope analysis, the FinHer regimen dominated the other two trastuzumab regimens, and was cost-effective compared to usual care (€1.845/QALY). In the decision-scope analysis, the HERA regimen was most effective, amounting to €50.746/QALY gained compared to FinHer. At a ceiling ratio of €30.000, the FinHer regimen was most likely to be cost-effective in both analyses. However, this probability was higher in the trial-scope analysis (98%) than in the decision-scope analysis (54%). Hence, the probability that in the real world a wrong decision is made is considerably higher than suggested in the trial-scope analysis. The parameter for which in the real world further research was most valuable was the credibility of the FinHer regimen. **CONCLUSIONS:** Incorporating parameters that improve generalizability is feasible, even in absence of evidence. Parameterizing the uncertainty of these parameters provides an estimation of how likely it is for each comparator to be cost-effective in the real world. Also, it informs decision-makers and researchers for which parameters further research is most valuable, for instance, in patient access schemes.

DIABETES/ENDOCRINE DISORDERS – Clinical Outcomes Studies

PDB1

HYPOGLYCEMIA-RELATED HEALTH-CARE UTILIZATION FOLLOWING INITIATION OF INSULIN ASPART IN A VIAL/SYRINGE OR IN A PREFILLED DISPOSABLE PEN (FLEXPEN®). ANALYSIS OF REAL-WORLD UTILIZATION IN THE UNITED STATES

Aagren M[1], Luo W[2]
[1]Novo Nordisk Inc, Princeton, NJ, USA; [2]Novo Nordisk Inc, Yardley, PA, USA

OBJECTIVES: Diabetes is a chronic and progressive disease that for many patients requires initiation and intensification of insulin in order to sustain glycemic control and thereby lower risk of long-term complications. Insulin intensification, however, can have some negative consequences for patients in the form of increased risk of hypoglycemic events. This analysis asks the question to what extent the administration vehicle, prefilled pen versus vial and syringe, has an impact on the risk of hypoglycemic events. **METHODS:** This is a retrospective database analysis comparing the incidence of hypoglycemia-related health-care utilization between patients that were previously naïve to short-acting insulin initiating the short-acting insulin analogue, insulin aspart (IAsp), in either a vial or in a prefilled disposable pen (FlexPen®). Data were derived from health-care claims for individuals with employer-sponsored primary or Medicare supplemental insurance between 2004 and 2007. The analysis was conducted using logistic regression technique controlling for age, gender, diabetes type, pre-index hypoglycemic incidence, pre-index diabetes treatments, and daily consumption of IAsp. Evaluation period was 12 months. **RESULTS:** The cohorts consisted of 5523 vial patients and 6065 FlexPen® patients. Mean age of the two cohorts were 53.6 and 56.2 years ($P < 0.0001$) in vial and FlexPen® groups, respectively. Fifty-one percent and 54% ($P = 0.05$) of the populations were males. Generally, a larger proportion the FlexPen® versus the vial cohort were already on an insulin regimen (basal or premix). Mean number of annual hypoglycemia-related health-care utilization incidence in the period following initiation of IAsp were 1.27 and 0.87 ($P < 0.0001$) for vials and FlexPen®, respectively. After multivariate adjustment, the odds ratio of hypoglycemic incidence with vials versus FlexPen® was 1.36 (CI: 1.20–1.54). **CONCLUSIONS:** After controlling for potential confounders, the incidence of hypoglycemia-related health-care utilization were 36% higher when initiating IAsp in a vial compared to initiation with FlexPen®.

PDB2

HOSPITALIZATIONS FOR SEVERE HYPOGLYCEMIAS IN PATIENTS WITH DIABETES MELLITUS IN SPAIN

Ramirez de Arellano A[1], Lindner L[2], Alvarez C[3], Sanchez-Zamorano M[1], De Rivas B[3], Badia X[2]
[1]Bristol-Myers Squibb Iberia, Madrid, Spain; [2]IMS Health, Barcelona, Spain; [3]AstraZeneca, Madrid, Spain

OBJECTIVES: To estimate the number of hospitalizations for severe hypoglycemia (SH) in patients with diabetes mellitus in Spain and assess the differences amongst regions. **METHODS:** A retrospective study was conducted using the hospital Minimum Basic Data Set (CMBD) which collects up to 73% of all hospitalizations in Spain. All hospitalization episodes of diabetic patients in which SH was the principal or secondary diagnosis for hospitalization during 2007 were accounted for. a SH was defined as a hypoglycemic episode which requires hospitalization. **RESULTS:** The number of SH episodes as primary diagnosis was estimated at 8242 in relation to total discharged patients with a diagnosis of DM2 (primary and secondary) at 496,660 patients (1.66% of total). When the number of SH as primary diagnosis is related to the total number of discharged patients with a diagnosis of DM2 as the primary diagnosis (23,343 patients), the percentage of episodes become 35.31%. The number of SH as a secondary diagnosis for hospitalization was estimated at 17,302 episodes: 16,649 in patients with DM2 (96.2%) and 653 in patients with DM1 (3.8%). For DM2 when SH as secondary diagnosis are added to primary diagnosis, the number of episodes is 24,891, which means that hypoglycemia diagnosis accounts for 5.01% of hospitalizations for DM2 patients (496,660 patients). Catalonia shows the highest number of SH, with 1477 episodes as a primary diagnosis in DM2 patients (17.9% of total) and 3836 episodes of SH as a secondary diagnosis in DM2 patients (23.0% of total). **CONCLUSIONS:** Severe hypoglycemia represents a significant cause for hospitalization for DM2 patients in Spain: incidence of 1.66% estimated in the overall DM2 patients increases to 35.3% in the subpopulation of patients discharged for DM2 as primary diagnosis. There is a great variation in the incidence of severe hypoglycemia between regions.

PDB3

EFFICACY AND SAFETY OF DIPEPTIDYL-PEPTIDASE 4 [DPP 4] INHIBITORS IN TYPE 2 DIABETES: META-ANALYSIS

Park H, Kim YA, Rascati KL
The University of Texas at Austin, Austin, TX, USA

OBJECTIVES: To assess the efficacy and safety of dipeptidyl peptidase-4 (DPP-4) inhibitors, including saxagliptin, sitagliptin, and vildagliptin, in type 2 diabetic patients. **METHODS:** Meta-analysis was conducted for efficacy (Hemoglobin A1c and weight) and safety outcomes (hypoglycemia and other adverse events). Both published and unpublished randomized controlled trials (RCTs) for type 2 diabetic patients using DPP-4 inhibitors were included. RCTs were selected if criteria included a duration of at least 12 weeks and they compared DPP-4 inhibitors with placebo or other hypoglycemic medications. Two reviewers independently assessed trials for inclusion and extracted data. Differences were resolved by consensus. **RESULTS:** Of 579 potentially relevant articles identified, 118 were retrieved for detailed evaluation, and 52 met inclusion criteria. DPP-4 inhibitors significantly reduced hemoglobin A1c compared with placebo (weighted mean difference, –0.851% [95% confidence interval {CI}, –1.057% to –0.645%]) and were noninferior to other hypoglycemic agents (0.117% [95% CI, –0.042% to 0.276%]). DPP-4 inhibitor increased weight compared with placebo (0.186 kg [95% CI, 0.128 kg to 0.244 kg]), but the increase was not significantly different from other hypoglycemic agents. Also compared with placebo, DPP-4 inhibitors had an increased risk of hypoglycemia (odd ratio [OR], 1.430 [95% CI, 1.198–1.708]) and any adverse event (OR, 1.072 [95% CI, 1.003–1.145]). However, the risk of experiencing hypoglycemia or any adverse event was significantly lower in patients using DPP-4 inhibitors compared to other hypoglycemic agents (OR, 0.307 [95% CI, 0.247–0.381]; OR, 0.828 [95% CI, 0.765–0.896], respectively). a similar result was also seen with serious adverse events (OR, 0.834 [95% CI, 0.699–0.996]) and GI adverse events (OR, 0.810 [95% CI, 0.715–0.917]) for DPP-4 inhibitors versus other oral antidiabetic medications. **CONCLUSIONS:** DPP-4 inhibitors had similar efficacy for hemoglobin A1c reduction and weight loss, and had a decreased risk of hypoglycemia and other adverse events compared with other hypoglycemic agents.

PDB4

A CROSS-SECTIONAL STUDY ON GLYCEMIC CONTROL AND ADVERSE EVENTS IN TYPE 2 DIABETES MELLITUS PATIENTS TREATED WITH ORAL ANTIDIABETIC DRUGS IN CHINA

Hu SL[1], Sun F[2], Xu ZR[3]
[1]Fudan University, Shanghai, China; [2]Novo Nordisk (China) Pharmaceuticals Co., Ltd., Beijing, China; [3]The 306th Hospital of PLA, Beijing, China

OBJECTIVES: The study reported the utilization of oral antidiabetic drugs (OADs), glycemic control, hypoglycemia, and adverse events of type 2 diabetes mellitus (T2DM) patients with OADs therapy during their clinical visits in urban hospitals in China. **METHODS:** The study was a cross-sectional survey conducted at 75 hospitals in nine cities in China. There were 9577 T2DM patients with OADs therapy completed the questionnaires. The survey period was from December 3, 2008 to July 31, 2009. Patients' self-report on their diabetes condition and the latest health examination was used to evaluate the diabetes management situation. Descriptive statistics method was used for the analyses. **RESULTS:** A total of 51.1% of the patients were male, the mean age (±SD) was 59.5 ± 12.7 years, and the mean duration of disease (±SD) was 7.9 ± 6.3 years. The percentage of patients treated with biguanides, sulfonylurea, meglitinides, glitazones, α-glucosidase inhibitors, and others (including traditional Chinese medicine) were 78.4%, 65.1%, 14.0%, 12.6%, 31.1%, and 18.1% respectively. Blood glucose control was inadequate, the mean HbA_{1c} and fasting blood glucose were 9.1 ± 2.4% and 9.4 ± 3.4 mmol/L, respectively. Only 7.9% of the patients achieved the treatment target ($HbA_{1c} < 6.5\%$). There were 15.3% patients who experienced hypoglycemia episodes in the last 4 weeks, the mean hypoglycemia rates were 26.0/patient/year, of which major hypoglycemia rates were 7.8/patient/year, and nocturnal hypoglycemia rates were 6.5/patient/year. There were 60.3% OADs